JUN 29 2009

510(k) Summary: DSU Dual Stage Ultrafilter

Submitter:	Nephros Inc. 41 Grand Ave River Edge, NJ 07661 Establishment Registration # 3003337893
Contact Person	Vikki M. O'Connor, Director QA/RA 41 Grand Ave River Edge, NJ 07661 201-207-2490 (p) 201-343-5207 (f) vhoffman@nephros.com
Date Prepared	March 30, 2009
Trade Name	DSU Dual Stage Ultrafilter
Proposed Class	Class II
Classification Name and Number	21 CFR Part 876.5665 Water Purification System for Hemodialysis
Product Code	FIP
Predicate Devices	FiberFlo™ Hollow Fiber Cartridge Water Filters – K983126
Device Description	The DSU Dual Stage Ultrafilter is a hollow fiber filter that removes bacteria, viruses, endotoxin and particulate from water and bicarbonate concentrate used in hemodialysis.
Intended Use	The DSU Dual Stage Ultrafilter is intended to be used to filter water or bicarbonate concentrate used in hemodialysis devices. The DSU assists in providing hemodialysis quality water or bicarbonate concentrate. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore it must be used in conjunction with other water treatment equipment (i.e., RO, DI, etc.).

Summary of the Technological Characteristics	The proposed device has the same technological characteristics and is similar in design as compared to the predicate device.
Assessment of Non-clinical Performance Data / Substantial Equivalence	The DSU Dual Stage Ultra Filter has been tested for performance. The tests conducted include Flow Rate versus Pressure Drop, Bicarbonate Composition Effect, Pyrogen Removal, Virus Challenge Test, Bacteria Challenge Test and Chemical Compatibility. This filter was found to be substantially equivalent to the predicate Minntech Fiberflo Filter (K983126).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

Ms. Vikki M. O'Connor
Director, QA/RA
Nephros, Inc.
41 Grand Avenue
RIVER EDGE NJ 07661

Re: K090885
Trade/Device Name: Nephros Inc. DSU Filter
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 30, 2009
Received: April 3, 2009

Dear Ms. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090885

Device Name: Nephros Inc. DSU Filter

Indications For Use:

The DSU Dual Stage Ultrafilter is intended to be used to filter water or bicarbonate concentrate used in hemodialysis devices. The DSU Ultrafilter assists in providing hemodialysis quality water or bicarbonate concentrate. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore, it must be used in conjunction with other water treatment equipment (i.e., RO, DI, etc.).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090885